DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 26 2010

Re: SABRIL
Docket No.: FDA-2010-E-0021

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 5,380,936, filed by Lundbeck Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for SABRIL (vigabatrin), the human drug product claimed by the patent.

The total length of the regulatory review period for SABRIL (vigabatrin) is 10,205 days. Of this time, 4,614 days occurred during the testing phase and 5,591 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: September 14, 1981.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 14, 1981.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: May 2, 1994.

   The applicant claims April 29, 1994, as the date the new drug application (NDA) for SABRIL (NDA 20-427) was initially submitted. However, FDA records indicate that NDA 20-427 was submitted on May 2, 1994.

3. The date the application was approved: August 21, 2009.

   FDA has verified the applicant's claims that NDA 20-427 (vigabatrin tablets) and NDA 22-006 (vigabatrin powder for oral solution) were approved on August 21, 2009.

Please note: we have determined that the regulatory review period for the human drug product, SABRIL, approved under NDA 20-427 for SABRIL Tablets, is the same as the regulatory review period determined for NDA 22-006 for SABRIL Powder for Oral Solution.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Edward P. Gamson
Husch, Blackwell, Sanders, Welsh & Katc, Ltd.
120 S. Riverside Plaza, 22 Floor
Chicago, IL 60606